June 18, 2019

Stryker Corporation
Paminder Khurmi
Staff Regulatory Affairs Specialist
4100 E Milham Ave
Kalamazoo, Michigan 49001

Re: K191049
Trade/Device Name: Stryker MIS and Footed Attachments
Regulation Number: 21 CFR 882.4310
Regulation Name: Powered Simple Cranial Drills, Burrs, Trephines, And Their Accessories
Regulatory Class: Class II
Product Code: HBE, ERL
Dated: April 18, 2019
Received: April 19, 2019

Dear Paminder Khurmi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Matthew Krueger, M.S.E.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191049

Device Name
Stryker MIS attachments

Indications for Use *(Describe)*
The MIS Attachments and Cutting Accessories are intended to be used with the Stryker Consolidated Operating Room Equipment (CORE®) Console and electric and pneumatic motors. When used with these motors, the MIS Attachments and Cutting Accessories are intended to cut bone in the following manner: drilling, reaming, decorticating, shaping, dissecting, shaving, and smoothing for the following medical applications: Neuro; Spine; Ear, Nose, and Throat (ENT)/ Otorhinolaryngology; and Endoscopic applications.
Specific applications include Craniotomy/Craniectomy, Laminotomy/Laminectomy, Minimally Invasive Surgery (MIS) Spine, Expanded Endonasal Approach (EEA)/Anterior Skull Base/ Endoscopic/Transnasal/Transphenoidal, and Orthopedic Spine.
These devices are also usable in the preparation for the placement of screws, metal, wires, pins, and other fixation devices.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191049

Device Name
Stryker Footed attachments

Indications for Use *(Describe)*
The Footed Attachments and Cutting Accessories are intended to be used with the Stryker Consolidated Operating Room Equipment (CORE®) Console and electric and pneumatic motors. When used with these motors, the Footed Attachments and Cutting Accessories are intended to cut bone in the following manner: drilling, reaming, dissecting, and shaping for the following medical applications: Neuro; Spine; Ear, Nose, and Throat (ENT) /Otology /Neurotology/ Otorhinolaryngology; Craniofacial and Maxillofacial; and Sternotomy.
Specific applications include Craniotomy/Craniectomy, Pterional Craniotomy, Sub Occipital/Retro Sigmoid/Posterior Fossa Craniotomy, Sphenoid Wing Dissection, Laminotomy / Laminectomy, and Orthopedic Spine.
These devices are also usable in the preparation for the placement of screws, metal, wires, pins, and other fixation devices.
It is also usable in the preparation for the placement of screws, metal, wires, pins, and other fixation devices.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k)Summary

This section provides a summary of 510(k) information in accordance with the requirements of 21 CFR 807.92.

I. SUBMITTER

510(k) Owner:	Stryker Instruments 4100 E. Milham Avenue Kalamazoo, Michigan 49001 USA Ph: +1-269-323-7700 Fax: +1-269-324-5412
Submitter/ Contact Person:	Paminder Khurmi Staff Regulatory Affairs Specialist Phone: +1-269-389-2264 Paminder.Khurmi@Stryker.com
FDA Establishment Registration No.	1811755
Date Submitted:	April 18, 2019

II. DEVICE

Trade Name:	Stryker® MIS and Footed Attachments
Common Name:	Surgical Drill Handpieces
Primary Classification	Drills, Burs, Trephines & Accessories (Simple, Powered) (21 CFR 882.4310, Product code HBE)
Secondary Classification	Drill, Surgical ENT (Electric or Pneumatic) including Handpiece (21 CFR 874.4250, Product code ERL)
Classification:	II

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III. PREDICATE DEVICE

510 (K) Number	Product code	Trade name	Manufacturer
K143540	HBE, ERL	Stryker® MIS Attachments and cutting accessories	Stryker Instruments
K143399	HBE, ERL	Stryker® Footed Attachments and cutting accessories	Stryker Instruments

IV. SUBJECT DEVICE DESCRIPTION

The Stryker MIS and Footed Attachments are used within a system consisting of a variety of devices, including a console, powered motors, and cutting accessories. The attachments connect to the motors and the cutting accessories to complete the system for physician use. The Stryker MIS and Footed Attachments are offered for prescription use only. The MIS and Footed Attachments are intended to serve as interfaces between powered motors and cutting accessories for the purposes of:

- Cutting bone, bone cement, and teeth;
- Placing or cutting screws, metal, wires, pins, and other fixation devices; and
- Providing a location for the user to hold and grip the device system.

The Stryker MIS Attachments are available in straight, curved and angled styles.

The Stryker Footed attachments are available as fixed footed, rotating footed, and non-footed attachments

The MIS and Footed Attachments are made of stainless steel (SST). All MIS and Footed Attachments have a color band on the proximal end of the outer surface to aid the user in correct system assembly. The color band serves to enhance the distinction of attachment and cutting accessory compatibility.

The Subject Devices Stryker MIS attachments and Stryker Footed attachments are cleared under two separate 510(k)s. Since the modification to the color band is identical for both attachment types (MIS and Footed), this premarket notification is being submitted as bundled submission in accordance with guidance document issued by FDA on June 22, 2007, “Bundling Multiple Devices or Multiple Indications in a Single Submission”.

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The purpose of this submission is to gain clearance for the color band modifications for the Subject Device Attachments color band that exceeds the threshold as per *FDA Guidance, "Deciding When to Submit a 510(k) for a Change to an Existing Device".*

V. INDICATIONS FOR USE

As the subject premarket notification is a bundled submission, there are 2 proposed indications for use, and are broken in 2 tables for each attachment type for easy navigation. See Table 1 below for Indications for Use for Stryker MIS attachments and Table 2 for Indications for Use for Stryker Footed attachments.

TABLE 1: COMPARISON OF INDICATIONS FOR USE FOR MIS ATTACHMENTS

	Subject Device- Stryker MIS attachments
Indications for Use	The MIS Attachments and Cutting Accessories are intended to be used with the Stryker Consolidated Operating Room Equipment (CORE®) Console and electric and pneumatic motors. When used with these motors, the MIS Attachments and Cutting Accessories are intended to cut bone in the following manner: drilling, reaming, decorticating, shaping, dissecting, shaving, and smoothing for the following medical applications: Neuro; Spine; Ear, Nose, and Throat (ENT)/Otorhinolaryngology; and Endoscopic applications. Specific applications include Craniotomy/Craniectomy, Laminotomy/Laminectomy, Minimally Invasive Surgery (MIS) Spine, Expanded Endonasal Approach (EEA)/Anterior Skull Base/ Endoscopic/Transnasal/Transphenoidal, and Orthopedic Spine. These devices are also usable in the preparation for the placement of screws, metal, wires, pins, and other fixation devices.

TABLE 2: COMPARISON OF INDICATIONS FOR USE FOR FOOTED ATTACHMENTS

	Subject Device- Stryker Footed attachments
Indications for Use	The Footed Attachments and Cutting Accessories are intended to be used with the Stryker Consolidated Operating Room Equipment (CORE®) Console and electric and pneumatic motors. When used with these motors, the Footed Attachments and Cutting Accessories are intended to cut bone in the following manner: drilling, reaming, decorticating, shaping, dissecting, shaving and smoothing for the following medical applications: Neuro; Spine; Ear, Nose, and Throat (ENT) /Otology /Neurotology/Otorhinolaryngology; Craniofacial and Maxillofacial; and Sternotomy.

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	Specific applications include Craniotomy/Craniectomy, Pterional Craniotomy, Sub Occipital/Retro Sigmoid/Posterior Fossa Craniotomy, Sphenoid Wing Dissection, Laminotomy / Laminectomy, and Orthopedic Spine. These devices are also usable in the preparation for the placement of screws, metal, wires, pins, and other fixation devices.

The Subject Device Indications for Use remains **identical** to the Predicate Devices. The modification described to the Subject Device in this 510(k) does not change the Indications for Use.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Subject Device is compared to the Predicate Device for substantial equivalence of technological characteristics based on the modification described in this submission.

Technological Characteristics

The only change in the Subject and Predicate Devices is the different color band.

The Color Band location, Attachment to Cutting Accessory Locking Mechanism, and Attachment to Motor Locking Mechanism are identical when comparing the Subject and Predicate Device and, all other technological characteristics, remains the same between the Subject and Predicate Devices.

The technological characteristics that are not the same between the Subject and Predicate Devices are the color band material and colorant. However, the Subject Device color band material and colorant are similar to those cleared for the Predicate Device, and the different characteristics do not raise different questions of safety and effectiveness.

VII. PERFORMANCE DATA

The following testing were performed, and the data was provided in support of the substantial equivalence determination:

Verification testing was performed on the Subject Devices as dictated by the results of the Risk Analysis, and no new questions of safety and effectiveness were raised. The Subject Device met all pre-defined acceptance criteria. The results of the tests mention in the Table 3, support the substantial equivalence of the Subject Device to the Predicate Device. Testing data from the following was provided in support of the substantial equivalence determination.

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TABLE 3. LIST IF TESTS PERFORMED

Tests performed	Results
Colorfastness and Durability test	Passed
Colorfastness Test	Passed

Biocompatibility Testing

A biocompatibility evaluation was performed following the recommendations of ISO 10993-1: 2018 and FDA Guidance (Use of International Standard ISO- 10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" June 2016) as appropriate for limited exposure (< 24 hours) externally communicating, tissue/bone/dentin devices. The following assessments were completed to further assess the potential risk of the subject device material and colorant modification impacting color additive release.

- Chemical Characterization: ICP-MS
- Toxicological Risk Assessment

The Biocompatibility testing was adopted from predicate submissions (K143540, K143399)

Animal Testing

Animal testing was not required as a basis for substantial equivalence.

Clinical Testing

Clinical testing was not required as a basis for substantial equivalence.

The Principle of Operation

The color band modification on the device does not change the Principle of Operation of the Subject Device compared to the Predicate Device.

The Principle of Operation remains: The Subject Device Attachments are combined with a power source, motor, and cutting accessory to achieve their function; the main function of the Subject Device Attachments is to provide a balanced location for the surgeon to hold and grip the device system, and to transmits torque from the motor to a cutting accessory.

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VIII. CONCLUSIONS

The subject devices, in comparison with the legally marketed predicates, have the same intended use, indications for use, operating principles, energy source, and functional outputs. Performance testing and risk analysis demonstrate that the devices are as safe and effective as the predicate devices and do not raise different significant questions of safety and effectiveness.